UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

SPRING PHARMACEUTICALS, LLC, Plaintiff, v. RETROPHIN, INC.; MARTIN SHKRELI; MISSION PHARMACAL COMPANY; ALAMO PHARMA SERVICES, INC.; and EVERSANA LIFE SCIENCE SERVICES, LLC, Defendants.	)	Case No. 2:18-cv-04553 JURY TRIAL DEMANDED **PUBLIC VERSION**

AMENDED COMPLAINT

NOW COMES Plaintiff Spring Pharmaceuticals, LLC ("Spring" or "Plaintiff"), by and through its undersigned counsel, and for its Complaint against Defendants Retrophin, Inc. ("Retrophin"); Martin Shkreli ("Shkreli"); Mission Pharmacal Company ("Mission"); Alamo Pharma Services, Inc. ("Alamo"); and Eversana Life Sciences Services, LLC ("Eversana") (collectively, "Defendants"), states as follows:

NATURE OF THE ACTION

1. This is an action for damages and permanent injunctive relief against Defendants for violations of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15(a) and 26, and state antitrust and unfair competition laws pursuant to the common laws of the Commonwealth of Pennsylvania.

2. Starting in 2014, Defendants established and maintained an unlawful monopoly over Thiola, a prescription pharmaceutical product used to treat patients suffering from a chronic

genetic disease known as cystinuria, which causes recurring kidney stones. The active ingredient in Thiola is tiopronin. Thiola is not covered by any patents or regulatory exclusivities. Despite being off-patent, there is no generic version of Thiola, precisely because Defendants' exclusionary and unlawful conduct has prevented and delayed the development of such a product. As detailed herein, Defendants acted in concert to manufacture and distribute Thiola on a direct-to-patient basis, a scheme designed to preclude generic entry, foreclose competition, and preserve monopoly power in violation of federal and state antitrust laws.

3. Despite its lack of patent protection, Thiola was the only tiopronin product approved by the federal Food and Drug Administration ("FDA") when Retrophin acquired the exclusive right to distribute the drug. As a result of Defendants' unlawful conduct, Plaintiff—a pharmaceutical company intending and preparing to bring a lower-cost, competing generic version of Thiola to market—was unable to access samples of Thiola to perform the testing required by FDA, and was thereby excluded from the marketplace. Defendants, meanwhile, have been able to set and preserve monopoly-level prices, leaving potential competitors, patients, health care payers, and taxpayers to suffer the effects of Defendants' illegal monopoly.

4. This unlawful monopoly was initially implemented by Defendant Martin Shkreli, the founder and original CEO of Retrophin. Under Shkreli's direction, Retrophin's business model was to acquire off-patent, sole-source drugs, move the drugs into a restricted distribution system designed to prevent generic entry, and raise their prices by staggering amounts.

5. Media reports on Thiola and other extraordinary price hikes on off-patent pharmaceutical products led to bipartisan congressional investigations by both the House of Representatives and the Senate. In December 2016, following its investigation, the Senate produced a 130-page report, entitled, "*Sudden Price Spikes in Off-Patent Prescription Drugs: The*

Monopoly Business Model that Harms Patients, Taxpayers, and the U.S. Health Care System" (the "Senate Report").[1]

6. As evidenced by the Senate Report and other public documents, Thiola is a prime example of Shkreli and Retrophin's monopolistic business model at work, in concert with Defendants Mission and Alamo.

7. Mission, a pharmaceuticals manufacturer, brought Thiola to market in the late 1980s. In May 2014, however, Mission entered into an agreement with Retrophin, pursuant to which Retrophin obtained an exclusive license to market, sell, and commercialize Thiola in the United States. Mission also agreed that it would not sell, distribute, or supply its own generic version of Thiola unless a third party's generic version of Thiola entered the market first. In exchange, Mission received a $3 million up-front payment, a guaranteed royalty tied to product sales, and additional compensation through the employment of its formerly owned sales-force subsidiary, Alamo.

8. Shortly after acquiring the rights to Thiola, Retrophin implemented its unlawful business plan: it removed the product from pharmacy shelves and moved Thiola into a closed distribution system—a strategy intended to "prevent[] generics from accessing the product[.]"[2] Thiola is only available through a single specialty pharmacy under Retrophin's careful watch: Dohmen Life Sciences Services, LLC ("Dohmen"). Dohmen was sold by its parent company, and the new owners changed the name in October 2018 to Eversana Life Science Services LLC, the defendant here. In exchange for its appointment by Retrophin as the sole pharmacy outlet for

[1] The Senate Report is available at: https://www.aging.senate.gov/imo/media/doc/Drug%20Pricing%20Report.pdf. The full compendium of public exhibits to the Senate Report is available at: *Sudden Price Spikes in Decades-Old Rx Drugs: Inside the Monopoly Business Model*, U.S. SENATE SPECIAL COMM. ON AGING (Mar. 17, 2016), https://www.aging.senate.gov/hearings/sudden-price-spikes-in-decades-old-rx-drugs-inside-the-monopoly-business-model.

[2] Senate Report Hr'g Ex. 18 at 8.

Thiola in the United States, Eversana agreed to, among other things, refuse any request by generic drug manufacturers to purchase Thiola. This distribution scheme thwarted generic competition by ensuring that generic manufacturers could not access sufficient quantities of Thiola necessary to develop a generic formulation and conduct the necessary head-to-head "bioequivalence" testing of their proposed generic formulation with Thiola, testing required by FDA to confirm that a generic version of an approved brand product is equivalently effective and safe for human use.

9. After acquiring exclusive rights to Thiola and moving it into a closed distribution system, Retrophin proceeded to spike the price of Thiola—a product Retrophin touted publicly as "an incredible medicine for people suffering from cystinuria" and "the standard of care for this disease."[3] Indeed, shortly after Retrophin acquired the rights to Thiola, a pharmaceutical product that first went on the market in 1988, Retrophin increased its price from $1.50 a tablet to $30 per tablet—***an increase of nearly 2,000%***. Moreover, Mission *expressly agreed* that it would not "sell, distribute, and supply its own generic version of [Thiola]" unless another first entered the market—an impossibility under Defendants' scheme.[4] In other words, Mission agreed to stay out of the market to prop up Thiola's price. The clear purpose and effect of Defendants' agreement was to unduly restrain trade. Retrophin's sudden exclusive right to market, sell, and commercialize Thiola quickly allowed for massive price increases benefitting only Defendants.

10. Internal documents showcase Retrophin's intent to exclude generic competitors and to price gouge the American public. In a May 3, 2014 email exchange with an investor, for example, Shkreli was candid about his motivation for acquiring Thiola: "The next generation of pharma guys (or the smart ones) understand the inelasticity of certain products. . .. We'd pay $1m

[3] Senate Report Hr'g Ex. 1 at 1.

[4] *See* Trademark License & Supply Agreement at 7, ECF No. 41-2.

to acquire a drug called Thiola, which is the only treatment for a rare disease called cystinuria . . .. The drug does $1.2m in sales. It is woefully underpriced and would not stop selling at orphan prices. With new pricing we estimate sales of $20 to $40 million. Almost 95% EBITDA margins . . .. A ***$100m present for you this morning***."[5]

11. With its investors, Retrophin was candid about the purpose of its restricted distribution system, highlighting it in one May 2014 presentation: "Closed distribution system ***prevents generics from accessing the product for bioequivalence studies***."[6] The company was equally blunt during its May 30, 2014 conference call announcing the Thiola deal: "We do not sell Retrophin products to generic companies."[7] Retrophin further noted, "The whole model that generics rely upon is turned upside down with specialty pharmacy distribution."[8]

12. Retrophin's rationale is clear: by preventing generics from purchasing samples necessary to conduct required testing, it precluded generics from entering the market at all—preserving its ability to set monopoly prices and reap supracompetitive profits from the sales of a vital health product.

13. After Shkreli left Retrophin in October 2014, Retrophin, Mission, Alamo, and Eversana continued to use—and profit from—the exclusive licensing agreement and restricted distribution scheme designed to prevent generic competition. Indeed, each of Retrophin, Mission, Alamo, and Eversana refused to sell samples of Thiola to Plaintiff, even at market price, and thereby prevented Plaintiff from conducting FDA-required studies and entering the marketplace. Since at least May 2014, Defendants' exclusive and anticompetitive scheme has worked to benefit

[5] Senate Report Hr'g Ex. 10 at 1-2 (emphasis added).

[6] Senate Report Hr'g Ex. 18 at 8 (emphasis added).

[7] Senate Report Hr'g Ex. 1 at 3.

[8] *Id.*

Defendants and to injure generics and consumers alike: there is no generic version of Thiola on the market, and the supracompetitive pricing of Thiola continues to benefit Defendants.

14. As alleged in detail below, Defendants repeatedly prevented and delayed Spring from entering the market with a competitive bioequivalent generic version of Thiola by refusing to sell Spring samples that would allow Spring to develop the generic product and obtain FDA approval [redacted] Spring seeks relief to redress these injuries caused by Defendants' anticompetitive scheme.

15. The Federal Trade Commission ("FTC") is investigating Retrophin, Eversana, and Mission for their unfair and anticompetitive business practices. Upon information and belief, in the summer of 2019, the FTC opened an investigation to determine whether Retrophin, Eversana, Mission, or their affiliates engaged in unfair methods of competition in violation of Section 5 of the FTC Act, 15 U.S.C. § 45, with regard to the development, sale, pricing, or marketing of certain drugs, including Thiola.[10]

PARTIES

16. Plaintiff Spring Pharmaceuticals, LLC is a Virginia limited liability company with its principal place of business in Virginia Beach, Virginia. Spring was formed on November 6, 2017, for the purpose of developing generic pharmaceuticals as alternatives to overpriced brand-name products.

[9] CDMOs are specialized service providers that develop and manufacture pharmaceutical products for client companies.

[10] Retrophin announced in August 2019 that it received a Civil Investigative Demand ("CID") from the FTC. Retrophin, Inc., Quarterly Report at 32 (Form 10-Q) (Aug. 6, 2019).

17. Defendant Retrophin, Inc. is a publicly traded corporation organized under the laws of the State of Delaware, with its principal place of business in San Diego, California. Retrophin sells three drugs, including Thiola. Martin Shkreli, then CEO of Retrophin, and others negotiated the subject Trademark License & Supply Agreement, dated May 29, 2014 (the "Agreement"), while working for Retrophin in New York, New York.

18. Defendant Martin Shkreli, an incarcerated individual, resides in Pennsylvania at Federal Correctional Institution Allenwood Low following his August 2017 conviction on securities fraud charges. Prior to his incarceration, Shkreli was domiciled in New York. Defendant Shkreli signed the Agreement on behalf of Retrophin.

19. Defendant Mission Pharmacal Company is a corporation organized under the laws of the State of Texas, with its principal place of business in San Antonio, Texas. Mission's "Commercial Office" is located at 77 N. Broad Street, Doylestown, Pennsylvania. Mission's Vice President of Corporate Business Development, located in Doylestown, Pennsylvania, negotiated the Agreement on behalf of Mission.

20. Defendant Alamo Pharma Services, Inc. is a corporation organized under the laws of the State of Delaware, with its principal place of business at 77 N. Broad Street, Doylestown, Pennsylvania. Alamo was formerly a wholly-owned subsidiary of Mission identified as the exclusive sales services provider to Retrophin under the Agreement.

21. Defendant Eversana Life Science Services, LLC is a limited liability company under the laws of Delaware, with its principal place of business at 190 N. Milwaukee Street Milwaukee, WI 53202. Eversana is registered to do business in Pennsylvania and has a physical business location in this District. Eversana serves as the exclusive pharmacy outlet for Thiola in the United States.

JURISDICTION AND VENUE

22. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 because this action arises under the antitrust laws of the United States, including Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, and Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15(a) and 26. Additionally, pursuant to 28 U.S.C. § 1367, this Court has supplemental jurisdiction over Plaintiff's state law claim, which arises from the same set of facts, and forms part of the same case or controversy, as its federal claims.

23. This Court has personal jurisdiction over Defendant Mission under 42 Pa. Cons. Stat. §§ 5301, 5322, and 15 U.S.C. § 22. Mission has engaged in systematic, purposeful, and continuous contacts in this judicial district. Mission's commercial office is located in this judicial district and, on information and belief, Mission transacts business by, among other things, offering to sell, selling, and shipping pharmaceutical products, including Thiola, into or through this judicial district.

24. This Court has personal jurisdiction over Defendant Alamo under 42 Pa. Cons. Stat. § 5301 and 15 U.S.C. § 22. Alamo is a corporation with its principal place of business in this judicial district and is registered to transact business in Pennsylvania as a foreign corporation. On information and belief, Alamo transacts business by, among other things, offering to sell and selling pharmaceutical products, including Thiola, throughout this judicial district. Moreover, Alamo has consented to personal jurisdiction in this forum in this litigation.

25. This Court has personal jurisdiction over Defendant Retrophin under 42 Pa. Cons. Stat. §§ 5301, 5322, and 15 U.S.C. § 22. Retrophin is registered to transact business in Pennsylvania as a foreign corporation and has been approved by the Pennsylvania Department of Human Services as a participating drug company in the State's Medical Assistance Program. On

information and belief, Retrophin transacts business by, among other things, offering to sell and selling pharmaceutical products, including Thiola, throughout this judicial district. Moreover, Retrophin has consented to personal jurisdiction in this forum in this litigation.

26. This Court has personal jurisdiction over Defendant Shkreli under 42 Pa. Cons. Stat. § 5322. Shkreli, among other things, negotiated and contracted with a Pennsylvania-based representative of Mission to supply, offer to sell, and sell pharmaceuticals in Pennsylvania, thereby causing anticompetitive harm in this judicial district. Additionally, this Court has personal jurisdiction over Shkreli because he is physically present and may be served with process in Pennsylvania.

27. This Court has personal jurisdiction over Defendant Eversana under 42 Pa. Cons. Stat. § 5322. Eversana is registered to transact business in Pennsylvania as a foreign corporation and has a physical presence in the district. On information and belief, Eversana, both now and when previously doing business under the name Dohmen Life Science Services, LLC, transacts business into or through this judicial district by, among other things, offering to sell, selling, and shipping pharmaceutical products, including Thiola, throughout this judicial district.

28. A substantial part of the events giving rise to the claims asserted in this Complaint took place in this judicial district. For example, Mission's business development representative negotiated and finalized the Agreement from his office in Doylestown, Pennsylvania.[11] This exclusive contract led to, and is in substantial furtherance of, the complained-of misconduct. Plaintiff also requested Thiola samples from Alamo's Doylestown, Pennsylvania office, and was denied those samples. On information and belief, certain Retrophin employees responsible for

[11] Senate Report Hr'g Ex. 17 at 1 (Email from Jim Self, Vice President of Corp. Bus. Dev., Mission, to Martin Shkreli, CEO, Retrophin (May 30, 2014) ("At Mission we have a [Business Development] team of 1")).

promoting Thiola are Pennsylvania residents. Thiola is listed on Pennsylvania's Medicare formulary and, on information and belief, patients located in the State of Pennsylvania are prescribed and use Thiola. On information and belief, doctors in Pennsylvania have received payments from Defendants Retrophin and Mission related to the promotion of Defendants' products. Moreover, Defendants Alamo, Mission, and Retrophin are found in and/or transact business in this district. Each Defendant is subject to personal jurisdiction in this judicial district. Venue is therefore proper in the Eastern District of Pennsylvania pursuant to 15 U.S.C. §§ 15 and 22, and 28 U.S.C. § 1391.

FACTUAL BACKGROUND

Statutory and Regulatory Background: Generic Competition

29. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act (commonly known as the "Hatch-Waxman Act") to ensure the availability of low-cost generic drugs for millions of Americans, recognizing the benefit of generic competition with respect to patient care and consumer savings. *See* 21 U.S.C. § 355(j).

30. Specifically, Congress authorized an expedited procedure for FDA approval of generic drugs, eliminating the need for a firm seeking to market a generic version of a brand manufacturer's product to conduct lengthy and expensive clinical trials to demonstrate its product's safety and efficacy. Instead, under the Hatch-Waxman Act, the generic firm may rely on the FDA's previous finding of safety and effectiveness with respect to the brand product—so long as the firm is able to demonstrate that the proposed generic is biologically equivalent to, and has the same active ingredients, route of administration, dosage form, strength, labeling, and conditions of use as, that brand drug. *See id.* §§ 355(j)(2)(A)(i)–(v). This demonstration establishes the generic as a bioequivalent product of the brand drug.

31. Under the governing statute, "[a] drug shall be considered to be bioequivalent to a listed drug" only if "the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses[.]" *See id.* § 355(j)(8)(B)(i). The "listed drug," in turn, refers to the particular FDA-approved brand drug at issue. *See id.* § 355(j)(7).

32. This means that generic manufacturers ***must obtain samples of the brand product*** in order to conduct FDA-required bioequivalence studies before being approved for the United States market. According to FDA, "[g]eneric manufacturers need anywhere from 2,000 to 5,000 doses of the branded drug in order to run studies to prove their generic medicine is the same as the branded drug."[12]

33. In June 2017, in an effort to promote generic competition, FDA began publishing a list of off-patent, off-exclusivity brand products without approved generics, including tiopronin (Thiola).[13] Shortly thereafter, in July 2017, FDA issued draft guidance on the recommended testing for approval of a generic version of Thiola. Specifically, the FDA recommends a two-way crossover in-vivo bioequivalence study comparing the proposed generic formulation to Thiola in test subjects. The FDA draft guidance further guides a generic applicant to "[c]onduct comparative

[12] *Statement from FDA Commissioner Scott Gottlieb, M.D., on new agency actions to further deter 'gaming' of the generic drug approval process by the use of citizen petitions*, U.S. FOOD & DRUG ADMIN. (Oct. 2, 2018), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm622252 htm.

[13] *FDA Tackles Drug Competition to Improve Patient Access*, U.S. FOOD & DRUG ADMIN. (June 27, 2017), https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm564725.htm; *see also List of Off-Patent, Off-Exclusivity Drugs without an Approved Generic*, U.S. FOOD & DRUG ADMIN. (Dec. 2019), https://www.fda.gov/media/133524/download.

dissolution testing on 12 dosage units each of all strengths of the test and reference product [*i.e.*, Thiola]."[14] Absent samples of Thiola, the necessary testing cannot be undertaken.

34. Usually, a generic manufacturer can purchase adequate amounts of the brand product for drug development and testing through normal distribution channels, such as through distributors, wholesalers, or pharmacies.

35. Then, once the generic manufacturer demonstrates bioequivalence and secures regulatory approval, including an "AB" rating from the FDA—a designation conveying that the generic alternative has satisfied bioequivalence standards—the generic version becomes subject to "automatic substitution" laws in effect in most states, including Pennsylvania. These substitution laws require or allow pharmacists to substitute the AB-rated generic version of a product for the brand product, unless the prescribing physician specifically requests otherwise.

36. However, when manufacturers of off-patent, branded products remove their products from normal distribution channels and block the sale of samples to would-be generic competitors, they undermine the very purpose of the Hatch-Waxman Act.

37. The Hatch-Waxman process, as described above, was designed "to speed the introduction of low-cost generic drugs to market." *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 404-05 (2012). Generic firms are typically able to offer lower prices than brand manufacturers because they do not need to replicate the brand manufacturers' costly and time-consuming clinical trials. Recent FDA analysis, for example, has confirmed the association between generic competition and lower prices, demonstrating that price reductions start with the

[14] *Draft Guidance on Tiopronin*, U.S. FOOD & DRUG ADMIN. 1 (Jul. 2017), https://www.accessdata.fda.gov/drugsatfda_docs/psg/Tiopronin_oral%20tablet_NDA%2019569_RC05-17.pdf.

first generic entrant.[15] The Government Accountability Office has reached the same conclusion, noting in one recent report that, "[o]n average, the retail price of a generic drug is 75% lower than the retail price of a brand-name drug."[16] As a result, the FTC has acknowledged, "there are . . . few things more effective in lowering the cost of prescription drugs than fostering substantial generic entry upon patent expiration, and letting competitive markets drive prices ever lower."[17]

38. Generics result in significant patient and taxpayer savings. According to one recent industry report, in 2017, generics generated a total of $265 billion in savings in the United States, including $82.7 billion in Medicare savings and $40.6 billion in Medicaid savings.[18]

39. The Hatch-Waxman process described above is a congressionally-mandated counterbalance between access and innovation—encouraged through exclusivity and patent periods—that remains a cornerstone of federal drug regulation today.

40. Anticompetitive conduct by brand manufacturers, though, threatens this very structure. The FDA, for example, has recently noted a pattern of "unfair and exploitative practices" by brand manufacturers "to frustrate or block the sale of a branded drug to a generic firm[,]"[19] despite that a "path to securing samples of brand drugs for the purpose of generic drug development

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[15] *New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices*, U.S. FOOD & DRUG ADMIN. (Dec. 13, 2019), https://www fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices.

[16] John E. Dicken, *Drug Pricing: Research on Savings from Generic Drug Use*, U.S. GOV'T ACCOUNTABILITY OFFICE 1 (Jan. 31, 2012), https://www.gao.gov/assets/590/588064.pdf.

[17] Maureen Ohlhausen, *Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics Workshop*, FED. TRADE COMM'N at 3-4 (Nov. 8, 2017), https://www.ftc.gov/system/files/documents/videos/understanding-competition-prescription-drug-markets-intro-keynote-remarks/ftc_understanding_competition_in_prescription_drug_markets_-_transcript_segment_1.pdf ("Understanding Competition in Prescription Drug Markets").

[18] *Generic Drug Access & Savings in the U.S.: Access in Jeopardy*, ASS'N FOR ACCESSIBLE MEDS. 4 (2018), https://accessiblemeds.org/sites/default/files/2018_aam_generic_drug_access_and_savings_report.pdf.

[19] *Remarks by Dr. Gottlieb at the FTC*, U.S. FOOD & DRUG ADMIN. (Nov. 8, 2017), https://www.fda.gov/NewsEvents/Speeches/ucm584195.htm.

should always be available" in order to "improve access and affordability."[20] As the former FDA Commissioner recently acknowledged, these "anticompetitive techniques" upset "the careful balance that Congress sought between product innovation and access."[21]

41. The FTC has also recognized the antitrust implications of when "[s]ome pharmaceuticals lose patent protection, but then draw no generic entry, allowing the incumbent firm to maintain high prices[,]" or when "speculators have [bought] up off-patent, single-source drugs and raised prices dramatically without drawing an immediate competitive response."[22]

Defendants' Anticompetitive Business Practices

42. Defendant Shkreli, previously a hedge fund manager, founded Retrophin in March 2011 and served as its CEO until October 2014. Retrophin describes itself as a pharmaceutical company focused "on the development, acquisition and commercialization of drugs for the treatment of serious, catastrophic or rare diseases for which there are currently no viable options for patients."[23] As detailed herein, however, Retrophin's playbook has three moves: first, acquiring off-patent, decades-old pharmaceutical products with no intention to invest in research and development; second, moving the products into a closed distribution system designed to prevent

[20] *Statement from FDA Commissioner Scott Gottlieb, M.D., on new agency efforts to shine light on situations where drug makers may be pursuing gaming tactics to delay generic competition*, U.S. FOOD & DRUG ADMIN. (May 17, 2018), https://www fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm607930.htm.

[21] *Statement from FDA Commissioner Scott Gottlieb, M.D., on new agency actions to further deter 'gaming' of the generic drug approval process by the use of citizen petitions*, U.S. FOOD & DRUG ADMIN. (Oct. 2, 2018), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm622252 htm.

[22] Understanding Competition in Prescription Drug Markets at 4.

[23] *Retrophin Accounts Agreement to Acquire Manchester Pharmaceuticals*, RETROPHIN (Feb. 12, 2014), http://ir retrophin.com/news-releases/news-release-details/retrophin-announces-agreement-acquire-manchester-pharmaceuticals.

generic competition; and third, re-pricing the products to reap supracompetitive profits at the expense of patient health and consumer welfare.

43. Under Shkreli's direction, Retrophin applied this business model to multiple commercial acquisitions. In February 2014, for example, Retrophin acquired non-party Manchester Pharmaceuticals LLC, a specialty pharmaceutical company focused on rare disease treatment. With this acquisition, Retrophin acquired the rights to Chenodal®, an FDA-approved pharmaceutical product.

44. In an investor presentation dated February 13, 2014, Retrophin touted Chenodal as an effective treatment for gallstones as well as the "standard of care" for CTX, a rare genetic disorder that—"without Chenodal treatment"—"can be lethal[.]"[24] Retrophin was unequivocal about its distribution plans for the drug—it quickly moved to a "[c]entric specialty pharmacy distributor" model, wherein "[abbreviated new drug application] filings are impossible unless generic company illegally penetrates specialty distributor [model]." This closed distribution system, as Retrophin frankly noted, "***does not allow for generics to access product for bioequivalence study***."[25]

45. Retrophin further highlighted its plans to employ a "specialty salesforce with a targeted commercial footprint."[26]

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[24] Senate Report Hr'g Ex. 3 at 5-7.

[25] *Id.* at 12 (emphasis added). Indeed, without the Thiola samples, it was impossible for Spring to submit an Abbreviated New Drug Application ("ANDA") to the FDA, putting Spring in a very different position than the plaintiff in *Roxane Labs., Inc. v. SmithKline Beecham Corp.*, No. 09-cv-1638, 2010 WL 331704 (E.D. Pa. Jan. 26, 2010). *See also Out Front Prods., Inc. v. Magid*, 748 F.2d 166, 168 (3d Cir. 1984) ("businesses that are hindered from forming or from entering a new market come within the zone of interests protected by the antitrust laws and may maintain suit for damages and for injunctive relief.").

[26] Senate Report Hr'g Ex. 59 at 2.

46. Retrophin's business model—closed distribution and specialty sales—created an artificial monopoly that allowed Retrophin to profit from price gouging. As Shkreli later boasted on a presentation slide entitled "Track Record of Successful Transactions," Retrophin "[i]ncreased Chenodal price 5x with no pushback from payors."[27]

47. Under Shkreli's direction, Retrophin replicated this same business model with respect to Thiola and implemented an even greater price increase.

48. According to emails produced in connection with the Senate investigation, a member of Retrophin's business development team "discovered the Thiola opportunity," which Shkreli saw as "very simple and Manchester [Pharmaceuticals] like."[28] On May 3, 2014, while the deal was "still a medium stage negotiation and may not come to fruition," Shkreli described the opportunity to an investor as follows: "We'd pay $1m to acquire a drug called Thiola, which is ***the only treatment for a rare disease called cystinuria*** . . . . The drug does $1.2m in sales. It is woefully underpriced and would not stop selling at orphan prices. With new pricing we estimate sales of $20 to $40 million. Almost 95% EBITDA margins . . .. A ***$100m present for you this morning***."[29]

49. Less than one month later, the licensing deal was done. As Jim Self—Mission's Vice President of Corporate Business Development—noted in a May 30, 2014 email to Shkreli, "This was seriously the fastest I've ever seen these types of deals get done. Nice job of removing the minutia and keeping the rails greased."[30]

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[27] *Id.*

[28] Senate Report Hr'g Ex. 1 at 3, Ex. 10 at 2.

[29] Senate Report Hr'g Ex. 10 at 2 (emphasis added).

[30] Senate Report Hr'g Ex. 17 at 1.

50. In terms of deal mechanics, Retrophin acquired an exclusive license to market, sell, and commercialize Thiola in the United States pursuant to the Agreement. In exchange, Mission received an upfront license fee of $3 million, in addition to guaranteed minimum royalties each year of $2 million or 20% of net sales.[31]

51. The Agreement also required Retrophin to appoint Alamo, then Mission's Pennsylvania-based subsidiary, as the "exclusive provider of sales force services" pursuant to an incorporated "Master Services Agreement," providing Mission an additional form of compensation under the exclusive deal.

52. Retrophin's documents and public filings reveal the integral and ongoing role that Alamo, Mission, and Eversana played (and continue to play) in Retrophin's business scheme. Alamo, for example, is referred to in Retrophin's documents as both "Mission's contract sales force business" and the "Retrophin nephrology/urology sales force"—a key piece of Retrophin's revenue-growth strategy.[32] Mission, meanwhile, is referred to as Retrophin's "great partner," with whom Retrophin planned—as early as May 2014—to develop a higher-dosage Thiola formulation to replace the existing, off-patent 100mg tablet.[33] Mission also agreed that it would only produce and sell a generic tiopronin product if a third party's generic tiopronin product somehow first entered the market, thereby literally withholding the benefits of generic competition from consumers.[34]

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[31] Retrophin, Inc., Annual Report at 8 (Form 10-K) (Mar. 11, 2015).

[32] Senate Report Hr'g Ex. 15 at 2, Ex. 18 at 9.

[33] Senate Report Hr'g Ex. 1 at 2-3 ("With our partner Mission, . . . [o]ur intent is to remove our legacy products from the channel as soon as new products are available, which is often called a 'hard switch.'"). Indeed, Retrophin began selling a patent-pending reformulation of Thiola in July 2019.

[34] *See* Trademark License & Supply Agreement at 7, ECF No. 41-2.

53. After acquiring the rights to Thiola, Retrophin moved the drug into closed distribution, candidly acknowledging in its Thiola-licensing investor call from May 2014: "We do not sell Retrophin products to generic companies. . .. The specialty pharmacy distribution model takes the AB substitutable rating that generics get and neuters it. . .. This whole model that generics rely upon is turned upside down[.]"[35]

54. Retrophin was equally blunt in its investor presentation from May 2014: "Similar to Chenodal, Retrophin will place Thiola into closed distribution. ***Closed distribution system prevents generics from accessing the product for bioequivalence studies***."[36]

55. Specifically, under its exclusive license, Retrophin appointed Defendant Eversana as the exclusive distributor of Thiola in the United States. Eversana acts as the exclusive "pharmacy" for patients and healthcare providers seeking Thiola. Both in intent and effect, this closed distribution system precluded sales of Thiola to generic manufacturers such as Plaintiff.

56. Protected from competition by its exclusive license and closed distribution system, Retrophin then significantly raised the price of Thiola. Indeed, despite acknowledging publicly that Thiola is the "standard of care" for cystinuria and promising to "understand the plight of patients who are abandoned by the pharmaceutical industry,"[37] Retrophin turned around and instituted an immediate price hike in accordance with Shkreli's drug pricing philosophy: "[d]rugs

[35] Senate Report Hr'g Ex. 1 at 3 (emphasis added). As described above, "AB substitutable" refers to generic drugs that have been approved by FDA as bioequivalent to a brand drug and thus subject to states' generic substitution laws, which require or allow pharmacists to substitute the AB-rated generic version for brand products, unless the prescribing physician specifically requests otherwise.

[36] Senate Report Hr'g Ex. 18 at 8 (emphasis added).

[37] Senate Report Hr'g Ex. 1 at 1-2.

are typically non-discretionary and consumers are relatively price insensitive . . .. ***Exclusivity (closed distribution) creates a barrier and pricing power***."[38]

57. Specifically, shortly after acquiring the rights to Thiola, Retrophin raised the product's price from $1.50 per tablet to $30.00 per tablet—an increase of nearly 2,000% for a drug that is initially dosed at three tablets per day.[39]

58. Later, Shkreli lauded this effort as a case study in "successful transactions"—"Increased price 21x with no pushback from payors."[40]

59. This conduct drew criticism from doctors and patients, caught the attention of the media, and prompted scrutiny from the government.[41] As noted above, beginning in November 2015, two United States Senators—Senator Susan Collins of Maine and Senator Claire McCaskill of Missouri—led a bipartisan investigation into select companies' drug pricing strategies, including Retrophin's. This investigation involved, among other efforts, three congressional hearings, the review of thousands of documents, and multiple interviews with patients, doctors, industry executives, and consumer advocates. As Senator McCaskill observed, "The hedge fund model of drug pricing is predatory, and immoral for the patients and taxpayers who ultimately foot the bill—especially for generic drugs that can be made for pennies per dose."[42]

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[38] Senate Report Hr'g Ex. 59 at 5 (emphasis added).

[39] Senate Report at 42.

[40] Senate Report Hr'g Ex. 59 at 3.

[41] *See, e.g.*, Ariana Eunjung Cha, *Senate launches investigation into drug pricing at 'pharma bro' company Turing, three others*, WASH. POST (Nov. 4, 2015), https://www.washingtonpost.com/news/to-your-health/wp/2015/11/04/senate-launches-investigation-into-drug-pricing-at-pharma-bro-company-turing-three-others/.

[42] *Collins, McCaskill Release Committee Report of Bipartisan Drug Pricing Investigation*, SUSAN COLLINS U.S. SENATOR FOR ME. (Dec. 21, 2016), https://www.collins.senate.gov/newsroom/collins-mccaskill-release-committee-report-bipartisan-drug-pricing-investigation.

60. Even after the congressional investigation into its business practices, Retrophin, in concert with Mission, Alamo, and Eversana, continue to implement, extend, and profit from the unlawful monopoly initially set up under Shkreli's direction.

61. Other senior executives at Retrophin were also involved in advancing this scheme. Steven Aselage—Retrophin's President and Chief Operations Officer when Shkreli was CEO, and successor CEO following Shkreli's departure—was acutely aware of efforts to prevent generics from obtaining samples. For example, an email to Mr. Aselage demonstrates that Retrophin executives actively monitored purchase orders to ensure that none of the interested purchasers were a "conduit for a generic manufacturer."[43]

62. In addition, the Agreement has been amended several times since Shkreli's resignation, including a March 2016 amendment to include the new development project for Thiola, and a November 2017 amendment to extend the initial license term through May 2029.

63. Mission, for its part, continues to manufacture and supply Thiola exclusively to Retrophin and obtains, by agreement, a direct financial benefit from its participation in this anticompetitive distribution scheme. On information and belief, Alamo continues to serve as the exclusive sales force services provider for Thiola, and thus financially benefitting from Retrophin's anticompetitive distribution scheme.

64. Retrophin's most recent 10-Q, filed on October 30, 2019, makes clear that it continues to view generics as a threat to its "sales and profitability," and it continues to operate the closed distribution system in concert with Mission and Alamo. As described above, this scheme had both the intent and effect of precluding any generic firm from acquiring samples of Thiola in sufficient quantities necessary to satisfy FDA-required bioequivalence testing.

[43] Senate Report Hr'g Ex. 37 at 1.

65. Furthermore, as described below, each of Retrophin, Mission, Alamo, and Eversana refused to sell samples of Thiola to Plaintiff, even at market prices, sacrificing short-term profits to achieve anticompetitive ends.

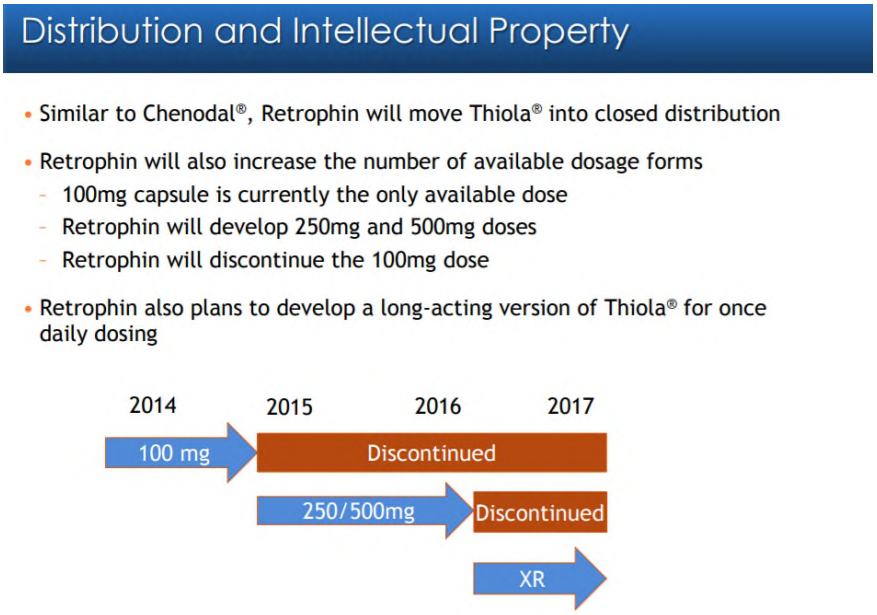
66. [redacted]

67. [redacted] Thiola EC purports to be a time-release version of Thiola. According to SEC filings, Retrophin has filed one or more patent applications covering Thiola EC. Visitors to www.thiola.com, Retrophin's website for Thiola, are confronted immediately with the following pop-up advertisement for Thiola EC:

This pop-up advertisement is evidence of a "soft switch," *i.e.*, Retrophin's attempt to persuade patients to purchase a new patent-pending drug instead of the unpatented existing Thiola. Soft switches are a type of product-hopping that monopolists use to preserve their monopoly position.

[redacted]

68. This soft switch is consistent with Retrophin's strategy of using product hopping to extend its monopoly and exclude generic competition for Thiola, as revealed in this PowerPoint slide mined from an archived version of Retrophin's website: [44]



69. [redacted]

[44] Retrophin Thiola License Presentation dated May 30, 2014, at 9 (archived on Oct. 5, 2014), http://web.archive.org/web/20141005103525/http:/www.retrophin.com/pdf/ThiolaInvestorCCPresentation.pdf.

[redacted]

70. [redacted]

Spring's Efforts to Develop a Generic Version of Thiola

71. Spring Pharmaceuticals, LLC was formed in November 2017 for the specific purpose of bringing new generic drugs to the U.S. market that would directly compete with existing off-patent, sole-sourced, and overpriced branded drugs used in the treatment of rare diseases. Prior to its formation, Spring's founders had selected a generic version of Thiola to be the company's first product.

72. Before Spring can market any generic version of Thiola, it must receive approval from the FDA that its proposed generic product is indeed "bioequivalent" to Thiola. Such approval is conditioned on testing that requires that Spring obtain samples of Thiola.

73. Accordingly, Spring contacted wholesalers, distributors, pharmacies, and other consultants about procuring Thiola samples. Spring was informed that Thiola was not available in normal distribution channels.

74. Spring turned to the exclusive licensee of the product—Retrophin. On January 17, 2018, Spring submitted a web inquiry through Retrophin's corporate website, noting that it was looking for product information. On January 18, 2018, a Retrophin representative e-mailed Spring and asked for additional details concerning Spring's request. In response, Spring explained that it

[redacted]

was seeking Thiola samples for generic drug development and asked to purchase the samples from Retrophin. Spring received no response from Retrophin to this request.

75. Meanwhile, on January 18, 2018, Spring wrote directly to the drug manufacturer, Mission, informing it that Spring was a generic pharmaceutical company developing a generic version of Thiola. Spring offered to purchase samples of Thiola. Spring did not receive a response from Mission.

76. On January 19, 2018, Spring faxed a similar letter to a number listed on Retrophin's Thiola web portal, again offering to purchase samples of Thiola for bioequivalence testing. In response, Spring received an email from Eversana stating that it would not sell Spring the requested Thiola samples.

77. Rebuffed by Mission, Eversana, and Retrophin, Spring pursued alternative channels through which it might obtain samples of Thiola, including two specialty pharmacies, both experienced in acquiring samples of branded pharmaceutical products for interested generic manufacturers, as well as a third company that advertises its ability to access an "extended variety" of pharmaceutical products. Spring was unable to procure Thiola from these sources.

78. In June 2018, Spring sent letters via certified mail to Retrophin and Mission again requesting the opportunity to purchase Thiola and stating its willingness to pay market prices for them. Once again, Spring received no response.

79. On August 9, 2018, Spring sent a letter to Alamo by certified mail, similar in form to the previous letters sent to Mission and Retrophin—requesting the opportunity to purchase Thiola samples and stating its willingness to pay market prices. Spring received no response.

80. Retrophin, Mission, Eversana, and Alamo each declined to sell the required samples to Spring, even at market prices. As a result, Spring could not commence the testing and

development necessary for FDA approval of a generic product. [redacted]

Spring's Intention and Preparedness to Enter the Relevant Market

81. Spring and its founders began preparing to develop a generic tiopronin product more than two and a half years ago. As early as April 2017, Spring's founders began discussions with pharmaceutical manufacturers, laboratories, and consultants [redacted] regarding the development of a generic version of Thiola. [redacted]

82. Spring began negotiations with multiple, experienced CDMOs in August 2017 regarding product development and manufacturing. [redacted]

[redacted]

[redacted]

83. [redacted]

[redacted]

[redacted]

84. [redacted]

85. [redacted]

[redacted]

[redacted] To that end, Spring will submit an ANDA containing the necessary data for the FDA to review and approve Spring's ANDA product.[59] The ANDA, which will be evaluated by FDA staff, includes four basic modules covering (1) administrative and prescribing information, (2) a "Quality Overall Summary" that provides an overview of the chemistry, manufacturing, and controls in place for the generic product, (3) detailed descriptions of the analytical procedures used to control quality and stability submitted as part of the ANDA, and (4) all clinical study report data needed to demonstrate that the generic product is bioequivalent to Thiola.[60] FDA publishes an ANDA "checklist" that assists applicants in ensuring that all parts of the ANDA have been properly submitted for FDA evaluation.[61] In the event that FDA has any questions or identifies any deficiencies in Spring's ANDA, it will notify Spring and allow Spring to resolve any issues and continue on towards approval.[62]

86. [redacted] FDA previously published "Draft Guidance on Tiopronin" that sets forth certain testing

[redacted]

[59] *See generally* Office of Generic Drugs, *Filing Review of Abbreviated New Drug Applications* (Sept. 1, 2017), https://www.fda.gov/media/107325/download.

[60] *See* FDA Center for Drug Evaluation and Research, *ANDA Submissions – Content and Format Guidance for Industry* (June 2019), https://www fda.gov/media/128127/download.

[61] *See* Office of Generic Drugs, *Filing Review of Abbreviated New Drug Applications* (Sept. 1, 2017), https://www.fda.gov/media/107325/download.

[62] *See* FDA Center for Drug Evaluation and Research, *Information Requests and Discipline Review Letters Under GDUFA Guidance for Industry* (Dec. 2017), https://www fda.gov/media/109915/download.

[redacted]

FDA recommends be presented for its consideration of the ANDA.[64] Spring will seek to expedite the review of its ANDA by obtaining a Competitive Generic Therapies ("CGT") designation for its ANDA product. CGT is a designation intended for applications for generic products where "there [is] inadequate generic competition for that drug, meaning there is not more than one approved drug in the active section of the Orange Book."[65] FDA may expedite the review of applications for products with CGT designations, and included tiopronin on its list of "drug products for which FDA could immediately accept an ANDA without prior discussion."[66] And because Thiola is not covered by any patents, FDA can approve the generic tiopronin product without further delay.

87. [redacted]

[64] *Draft Guidance on Tiopronin*, U.S. FOOD & DRUG ADMIN. 1 (Jul. 2017), https://www.accessdata.fda.gov/drugsatfda_docs/psg/Tiopronin_oral%20tablet_NDA%2019569_RC05-17.pdf.

[65] *Statement from FDA Commissioner Scott Gottlieb, M.D., on new policy to improve access and foster price competition for drugs that face inadequate generic competition*, U.S. FOOD & DRUG ADMIN. (Feb. 15, 2019), https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-policy-improve-access-and-foster-price-competition; *see also* FDA Center for Drug Evaluation and Research, *Competitive Generic Therapies Guidance for Industry* (Feb. 2019), https://www fda.gov/media/125134/download.

[66] *List of Off-Patent, Off-Exclusivity Drugs without an Approved Generic*, U.S. FOOD & DRUG ADMIN. (Dec. 2019), https://www.fda.gov/media/133524/download.

[redacted]

[redacted]

88. The defining characteristic of a generic equivalent is that its reference listed drug ("RLD"), including its active ingredient, has already been determined to be safe and effective by the FDA in approving the RLD. Accordingly, a generic applicant can expect that so long as it develops its product to be bioequivalent to the RLD, its ANDA will be approved. [redacted], Spring believes that the FDA will approve its bioequivalent generic tiopronin product following review of Spring's ANDA submission. And considering Thiola (and Spring's generic equivalent) is a small molecule, immediate release oral tablet product containing only one active pharmaceutical ingredient,[69] Spring believes that FDA approval of Spring's ANDA is certain.

89. Indeed, bioequivalent oral solid tablet ANDA products are considered 100% approvable, provided that the ANDA applicant is willing to address any deficiencies identified by the FDA in its application. Stated differently, there is no legal, regulatory, or scientific reason why a bioequivalent oral solid tablet ANDA product will not be approved. This is why FDA determined that tiopronin should be classified in Part I of the FDA's List of Off-Patent, Off-Exclusivity Drugs without an Approved Generic.[70] Unlike complex generic drugs classified in Part II, for which

[redacted]

[69] *See* Chia-Ying Lee et al., *Forces influencing generic drug development in the United States: a narrative review*, J. PHARM. POL. PRAC. 9:26, 2016, at 3, *available at* https://www ncbi nlm nih.gov/pmc/articles/PMC5034442/pdf/40545_2016_Article_79.pdf (explaining that "small molecule pharmaceutical products are simpler to create" and that "solid oral forms (e.g., tablets, capsules) and parenteral solutions have a higher likelihood of being easily developed").

[70] *See List of Off-Patent, Off-Exclusivity Drugs without an Approved Generic*, U.S. FOOD & DRUG ADMIN. (Dec. 2019), https://www.fda.gov/media/133524/download; *see also List of Off-Patent, Off-Exclusivity Drugs without an Approved Generic*, U.S. FOOD & DRUG ADMIN. (Dec. 13, 2019), https://www fda.gov/drugs/abbreviated-new-drug-application-anda/list-patent-exclusivity-drugs-without-approved-generic.

"ANDA development or approval may raise potential legal, regulatory, or scientific issues that should be addressed with the Agency prior to considering submission of an ANDA," Part I drugs, including tiopronin, do not present such approvability hurdles, and thus "FDA could immediately accept an ANDA without prior discussion."[71] Thus, approval of Spring's ANDA is objectively virtually certain, assuming Spring satisfies the FDA's application requirements and any subsequent request from the FDA, which Spring fully intends to do.

90. [redacted]

[71] *List of Off-Patent, Off-Exclusivity Drugs without an Approved Generic*, U.S. FOOD & DRUG ADMIN. (Dec. 13, 2019), https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/list-patent-exclusivity-drugs-without-approved-generic.

[redacted]

91. Once the product is approved, Spring plans to distribute and sell its generic version of Thiola, and to compete head-to-head with Retrophin, Mission, Alamo, and Eversana. Spring's sales burdens are substantially lessened by substitution laws that allow pharmacists to substitute Spring's generic version for branded Thiola. [redacted]

92. [redacted]

93. [redacted]

Relevant Product Market and Geographic Market

94. The relevant product market in which to assess the anticompetitive effects of Defendants' conduct is the United States market for FDA-approved tiopronin pharmaceutical

[redacted]

products; that is, Thiola, Thiola EC, and any FDA-approved generic version thereof (the "Relevant Market").

95. As noted above, Thiola treats patients suffering from cystinuria—a chronic genetic disease that causes recurring kidney stones.

96. On information and belief, cystinuria afflicts about 1 in every 10,000 persons, with approximately 33,000 cases in the United States as of 2019.

97. In terms of drug treatment for cystinuria in the United States, there were no substitutes for Thiola until July 2019, and even now the only substitutes are Defendants' Thiola EC products. Retrophin documents made this clear, characterizing Thiola as the "standard of care" for cystinuria, with the other potential drug product—Cuprimine®—targeted as "inferior" and "toxic" in terms of safety and efficacy.[78] As Retrophin explained to market analysts, Cuprimine is primarily indicated for a different disease, and in any event, "[p]hysicians prefer Thiola over Cuprimine because the adverse event profile for Thiola is better. Cuprimine is a very harsh therapy and patients who are allergic to penicillin are also allergic to penicillamine. Thiola is also believed to be more efficacious[.]"[79] The lack of substitutability is further evidenced by Retrophin's boasting that it "[i]ncreased price 21x with no pushback from payors,"[80]—an increase well in excess of the 5% price increase economists generally use to determine whether products are substitutes.[81]

[78] Senate Report Hr'g Ex. 1 at 1-2.

[79] Senate Report Hr'g Ex. 20 at 1.

[80] Senate Report Hr'g Ex. 59 at 3.

[81] If a seller increases the price of its product by 5% and consumers react by switching to a different product, those two products are typically considered to be in the same market. *See Horizontal Merger Guidelines*, U.S. DEP'T OF JUSTICE § 4.1 (Aug. 19, 2010), https://www.justice.gov/atr/horizontal-merger-guidelines-08192010.

98. Indeed, the lack of substitutes and the inelasticity of demand was precisely why Retrophin targeted Thiola for its commercial portfolio in 2014. As Shkreli told one investor in early May 2014, "[t]he next generation of pharma guys (or the smart ones) understand the inelasticity of certain products. . .. We'd pay $1m to acquire a drug called Thiola, which is the only treatment for a rare disease called cystinuria."[82]

99. Retrophin reported net product sales of nearly $55 million from Thiola in 2015. Those sales increased to $71 million in 2016, $82 million in 2017, and $89 million in 2018.[83]

100. Thiola is off patent and is not protected by any other exclusivity period.

101. Thiola is not subject to an FDA-approved Risk Evaluation and Mitigation Strategies ("REMS") protocol.[84]

102. Pending the expected regulatory approval, the lower-cost, generic tiopronin product developed by Spring would be bioequivalent to Thiola and subject to states' automatic substitution laws.[85]

103. Courts have recognized that a specific brand product, and a potential generic with the same active ingredient, may constitute the relevant product market for antitrust purposes.

104. The relevant geographic market is the United States of America. FDA regulatory requirements apply to all drugs sold in the United States. On information and belief, Thiola is distributed by Defendants to patients located throughout the United States.

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[82] Senate Report Hr'g Ex. 10 at 1-2.

[83] Retrophin, Inc., Annual Report at 46 (Form 10-K) (Feb. 27, 2018); Retrophin, Inc. Annual Report at 47 (Form 10-K) (Feb 26, 2019).

[84] A REMS protocol is a regulatory protocol implemented by the FDA to restrict access to certain drugs that pose potential safety risks to consumers.

[85] Most states have "automatic substitution" laws, which require or allow pharmacists to substitute the AB-rated generic version for brand products, unless the prescribing physician specifically requests otherwise.

105. Retrophin, as the exclusive licensee of Thiola in the United States, is the only company with an FDA-approved tiopronin product. As a result, at all times relevant to this Complaint, Retrophin has possessed a 100% market share in the Relevant Market and, indeed, has complete market dominance in the relevant product and geographic markets.

106. Retrophin maintains this monopoly, in concert with Mission, Eversana, and Alamo, through a closed distribution system, precluding generic entry into the marketplace.

Spring's Damages and Antitrust Injury

107. The actual and continuing injuries to both Spring and competition flow directly from Defendants' anticompetitive conduct. As described in detail above, Defendants' exclusionary conduct prevented, [redacted], Spring's entry into the market as a generic competitor. By implementing a closed distribution scheme and actively policing sales and product inquiries to completely eliminate the possibility of generic competitors acquiring the samples of Thiola necessary for bioequivalence testing, Defendants foreclosed the possibility of generic competition and fortified their monopoly position.

108. Defendants' conduct caused substantial harm to the competitive process as well as to individual consumers, healthcare payers, government payers, and taxpayers, all of whom have been deprived of the primary benefits of generic competition—equivalent products at lower prices. The anticompetitive effects of Defendants' conduct are evident from the staggering Thiola price increases. Defendants' refusal to deal with potential generic competitors on commercially reasonable terms, coupled with the Thiola price increases, reveal a predatory intent to stifle competition at the expense of consumers.

109. There are no pro-competitive justifications for Defendants' refusal to deal. Their conduct can only be explained by anticompetitive motives, and a desire to foreclose competition

in the Relevant Market. Any proffered justification is mere pretext. As Senator Collins noted in connection with the Senate's investigation into Retrophin's business practices:

> There's absolutely no reason, according to the medical experts that we've talked to, to put this drug into a specialty pharmacy or a restricted distribution system other than to prevent generics from buying up enough of the drug to produce a lower-price generic version. The only exceptions are drugs that have special safety risks. And that is not the case here according to what the experts tell us.[86]

110. As detailed above, Spring exhausted all possible legal sources to acquire the Thiola samples necessary for generic development. As a result of Defendants' exclusionary and anticompetitive conduct, Spring was prevented from and/or delayed in securing regulatory approval and entering the Relevant Market, causing Spring significant harm, including substantial lost revenue and profits based on product sales. Spring will also be required to pay higher development costs.

111. Absent this anticompetitive refusal to deal, Spring would have entered the Relevant Market much earlier, and secured a large market share with substantial sales through lower prices and effective marketing.

112. Defendants' exclusionary and unlawful conduct has injured competition, competitors like Spring, consumers, and patients alike, while Defendants continue to reap supracompetitive profits through the maintenance of the illegal tiopronin monopoly.

[86] Senator Susan Collins, *Sudden Price Spikes in Decades-Old Rx Drugs: Inside the Monopoly Business Model*, U.S. SENATE SPECIAL COMM. ON AGING, 03:10:18-03:11:00 (Mar. 17, 2016), https://www.aging.senate.gov/hearings/sudden-price-spikes-in-decades-old-rx-drugs-inside-the-monopoly-business-model.

COUNT I

Sherman Act Section 2
Monopolization and/or Attempted Monopolization – Retrophin

113. Plaintiff re-alleges and incorporates by reference paragraphs 1–112 as if fully set forth herein.

114. As detailed above, Retrophin has monopoly power in the Relevant Market, including the power to control prices. This complete monopoly will remain in place until it is contested by a bioequivalent FDA-approved generic alternative reaching the market.

115. As alleged herein, Retrophin willfully and intentionally engaged in anticompetitive conduct in order to unlawfully acquire and maintain its monopoly in the Relevant Market, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

116. Specifically, Retrophin unlawfully monopolized the Relevant Market through, among other anticompetitive acts:

a. Entering into exclusive dealing contracts with Defendants Mission, Alamo, and Eversana;

b. Moving Thiola into a restricted distribution system designed to exclude generic competition;

c. Actively monitoring orders to ensure that generic manufacturers do not obtain necessary product samples;

d. Extending the monopoly through contract amendments;

e. Artificially seeking to extend the monopoly through soft-switch "product hopping" efforts;

f. Refusing to sell necessary samples to a generic manufacturer at market prices; and,

g. Failing to negotiate on commercially reasonable terms, [redacted].

117. Retrophin's conduct occurred in, and has had a substantial effect on, interstate commerce in the United States.

118. As a direct, foreseeable, and proximate result of Retrophin's anticompetitive and monopolistic conduct, Spring suffered commercial and competitive injuries, with resultant damages in amounts to be proven at trial, including at least in the following ways: (i) Spring was foreclosed, or at the very least delayed, from competing in the Relevant Market; (ii) Spring lost revenue from lost product sales and business opportunities; and (iii) Spring incurred significant costs and fees.

119. As a direct, foreseeable, and proximate result of Retrophin's anticompetitive and monopolistic conduct, the competitive process as well as individual patients and payors in the Relevant Market have been harmed by, among other things, (i) Retrophin's ability to charge supracompetitive prices for Thiola, and (ii) reduced choice and diminished access to effective drug treatments.

120. [redacted] Spring has been directly harmed and has suffered direct antitrust injury by Retrophin's anticompetitive and monopolistic conduct and the resulting harm to competition in at least the following ways: (i) Spring has been illegally blocked from developing a competing generic product that would lower prices for consumers; and (ii) Spring has been illegally blocked from offering a competing product to consumers.

121. In the alternative, Retrophin has denied access to essential goods, services, or resources necessary to compete in the Relevant Market, constituting a violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

122. As detailed above, Retrophin has monopoly control over Thiola. Thiola is an essential resource for FDA-required bioequivalence testing. Retrophin's distribution of Thiola, thus, is an essential facility for the development and production of the generic version of Thiola.

123. Spring was practicably unable to procure these samples from an alternate source, to reasonably duplicate the product, or to otherwise conduct the testing necessary to file an abbreviated new drug application for its generic version of Thiola.

124. It was feasible for Retrophin to provide the Thiola samples on commercially reasonable terms.

125. By implementing a closed distribution system and refusing to provide Spring with essential samples, despite Spring's willingness to pay market prices, Retrophin denied access to an essential resource and has wrongfully maintained its monopoly power with respect to Thiola, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

126. Retrophin has no procompetitive, legitimate business justification for sacrificing profits by refusing to sell samples of Thiola to Spring on commercially reasonable terms. Its conduct can be explained only by anticompetitive motives, including the desire to thwart generic competition in the Relevant Market.

127. Courts have recognized that a brand drug manufacturer's refusal to deal with, and/or provide necessary samples to, a generic drug manufacturer may give rise to liability under the essential facilities doctrine.

128. As a result of Retrophin's unlawful denial of access to an essential facility or resource, Spring suffered and continues to suffer injury to its business and property, including lost profits, costs and fees, and lost business opportunities.

129. As a result of Retrophin's unlawful denial of access to an essential facility or resource, the competitive process has suffered, and continues to suffer. In particular, competition in the Relevant Market continues to be restrained and foreclosed. The lack of competition deprives patients and payors of its primary benefits—more choices and lower prices.

130. Spring has been directly harmed and has suffered direct antitrust injury by Retrophin's unlawful denial of access to an essential facility or resource and the resulting harm to competition in at least the following ways: (i) Spring has been illegally blocked from developing a competing generic product that would lower prices for consumers; and (ii) Spring has been illegally blocked from offering a competing product to consumers.

131. Spring requests and is entitled to a judgment that Retrophin has violated Section 2 of the Sherman Act, 15 U.S.C. § 2; to the damages it suffered as a result of that violation, to be trebled in accordance with the Clayton Act, 15 U.S.C. § 15; and to its costs and attorneys' fees; and to an injunction restraining Retrophin's continued violations.

COUNT II

Sherman Act Section 2
Conspiracy to Monopolize – All Defendants

132. Plaintiff re-alleges and incorporates by reference paragraphs 1–131 as if fully set forth herein.

133. As detailed above, Retrophin has monopoly power in the Relevant Market, including the power to control prices. This complete monopoly will remain in place until it is contested by a bioequivalent, FDA-approved, generic alternative reaching the market.

134. As alleged herein, Defendants Shkreli, Retrophin, Mission, Alamo, and Eversana entered into exclusive agreements with the specific intent to monopolize the Relevant Market, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, and similar state laws.

135. Each Defendant also took overt acts in furtherance of this conspiracy, as alleged in detail elsewhere in this Amended Complaint.

136. Defendant Shkreli instituted the complained-of unlawful scheme: causing Retrophin to acquire rights in an off-patent, decades-old drug, with the specific intent to move the drug into a restricted distribution scheme designed to prevent generic entry, and to thereafter set and preserve monopoly-level prices, causing harm to potential competitors and consumers.

137. Shkreli and Retrophin accomplished this scheme by entering into exclusive agreements with Mission and Alamo—entities that stood to profit from, and in fact perpetuated, the unlawful contractual and distribution scheme, even after Shkreli's departure, and even after media and governmental scrutiny of Retrophin's business practices.

138. Most recently, by means of their refusal to provide essential samples to Spring, each of Retrophin, Mission, Alamo, and Eversana has acted for the specific purpose of, and in furtherance of, monopolizing the Relevant Market.

139. Defendants' conduct occurred in, and has had a substantial effect on, interstate commerce in the United States.

140. As a direct, foreseeable, and proximate result of Defendants' conspiratorial and anticompetitive conduct, Spring suffered commercial and competitive injuries, with resultant damages in amounts to be proven at trial, including at least in the following ways: (i) Spring was foreclosed, or at the very least delayed, from competing in the Relevant Market; (ii) Spring lost

revenue from lost product sales and business opportunities; and (iii) Spring incurred significant costs and fees.

141. As a direct, foreseeable, and proximate result of Defendants' conspiratorial and anticompetitive conduct, the competitive process as well as individual patients and payors in the Relevant Market have been harmed by, among other things, (i) Defendants' preservation of supracompetitive prices for Thiola, and (ii) reduced choice and diminished access to effective drug treatments.

142. Spring has lost sales and profits and will continue to lose sales and profits, and consumers have suffered and will continue to suffer from the lack of generic price competition, if Defendants' unlawful conduct is not enjoined. Spring was directly harmed and suffered direct antitrust injury by Defendants' anticompetitive and monopolistic conduct and the resulting harm to competition in at least the following ways: (i) Spring has been illegally blocked from developing a competing generic product that would lower prices for consumers; and (ii) Spring has been illegally blocked from offering a competing product to consumers.

143. In the alternative, Defendants have conspired to deny access to essential goods, services, or resources necessary to compete in the Relevant Market, constituting a violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

144. As detailed above, Thiola is an essential resource for FDA-required bioequivalence testing. Defendants' distribution of Thiola, thus, is an essential facility for the development and production of a generic version of Thiola.

145. Spring was practicably unable to procure these samples from an alternate source, to reasonably duplicate the product, or to otherwise conduct the testing necessary to file an abbreviated new drug application for its generic version of Thiola.

146. It was feasible for each Defendant to provide, or authorize the provision of, Thiola samples on commercially reasonable terms.

147. By instituting and preserving a closed distribution system designed to prevent generic entrants, and by refusing to provide Spring with essential Thiola samples, despite Spring's willingness to pay market prices, Defendants conspired to deny access to an essential resource, allowing Retrophin to unlawfully maintain its monopoly power with respect to Thiola, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

148. Defendants have no procompetitive, legitimate business justification for sacrificing profits by refusing to sell samples of Thiola to Spring at market prices. Their conduct can be explained only by anticompetitive motives, including the desire to thwart generic competition in the Relevant Market.

149. As a result of Defendants' unlawful denial of access to an essential facility or resource, Spring suffered and continues to suffer injury to its business and property, including lost profits, costs and fees, and lost business opportunities.

150. As a result of Defendants' unlawful denial of access to an essential facility or resource, the competitive process suffered, and continues to suffer. In particular, competition in the Relevant Market will continue to be restrained and foreclosed. The lack of competition will deprive patients and payors of its primary benefits—more choices and lower prices.

151. Spring was directly harmed and suffered direct antitrust injury by Defendants' unlawful denial of access to an essential facility or resource and the resulting harm to competition in at least the following ways: (i) Spring has been illegally blocked from developing a competing generic product that would lower prices for consumers; and (ii) Spring has been illegally blocked from offering a competing product to consumers.

152. Spring requests and is entitled to a judgment that Defendants have conspired to violate Section 2 of the Sherman Act, 15 U.S.C. § 2; to the damages it suffered as a result of that violation, to be trebled in accordance with the Clayton Act, 15 U.S.C. § 15; and to its costs and attorneys' fees; and, to an injunction restraining Defendants' continued violations.

COUNT III

Sherman Act Section 1
Conspiracy in Restraint of Trade – All Defendants

153. Plaintiff re-alleges and incorporates by reference paragraphs 1–152 as if fully set forth herein.

154. As detailed above, and through the foregoing acts, Defendants entered into a continuing contract, combination, or conspiracy to unreasonably restrain trade and commerce in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1, by artificially reducing or eliminating competition in the Relevant Market.

155. Specifically, beginning in May 2014 and continuing through to the present, Defendants acted in concert to thwart competition in the Relevant Market by entering into—and continuing to amend and prolong—an exclusive licensing agreement, and corollary services agreement, in furtherance of Shkreli's and Retrophin's anticompetitive business model.

156. These exclusionary agreements are unreasonably restrictive in terms of duration and market coverage, as they impede the supply and sale of Thiola and serve the anticompetitive purpose of precluding generic competition in the marketplace.

157. Pursuant to these agreements, Mission, Alamo, and Eversana continue to profit from, and participate in, the exclusionary and unlawful distribution scheme initially devised by Shkreli and, to this day, perpetuated by Retrophin in concert with Mission and Alamo.

158. The anticompetitive effects of this concerted conduct are clear: generic entrants are precluded from entering the marketplace, and patients and payors are deprived of lower-cost, generic alternatives to Thiola.

159. Defendants' unlawful and concerted conduct occurred in, and has had a substantial effect on, interstate commerce in the United States.

160. As a result of Defendants' unlawful and concerted conduct, effectuated through exclusive and unjustified agreements, Spring has suffered and will continue to suffer injury to its business and property, including lost profits, costs and fees, and lost business opportunities.

161. Spring requests and is entitled to a judgment that Defendants' exclusionary and concerted conduct violates Section 1 of the Sherman Act, 15 U.S.C. § 1; to the damages it suffered as a result of that violation, to be trebled in accordance with the Clayton Act, 15 U.S.C. § 15; to its costs and attorneys' fees; and to an injunction restraining Defendants' continued violations.

COUNT IV

Pennsylvania State Law of Unfair Competition – All Defendants

162. Plaintiff re-alleges and incorporates by reference paragraphs 1–161 as if fully set forth herein.

163. In violation of the common law of the State of Pennsylvania, Defendants unfairly competed with Spring by entering into, and continuing, an exclusive and unlawful business arrangement designed to impede generic competition and to artificially preserve a monopoly at the expense of consumer health and welfare. Defendants also unfairly competed with Spring by refusing to sell necessary Thiola samples to Spring despite its willingness to pay market prices.

164. Defendants' conduct constitutes unfair competition because it violates standards of commercial morality and has substantially interfered with Plaintiff's ability to compete on the

merits of its product, and otherwise conflicts with accepted principles of public policy recognized by antitrust laws and other common law.

165. Defendants' unfair competition occurred in a course of conduct involving trade or commerce.

166. Spring suffered actual damages that were proximately caused by Defendants' unfair competition, including for the reasons set forth above.

RELIEF REQUESTED

WHEREFORE, for the foregoing reasons, Plaintiff Spring Pharmaceuticals, LLC respectfully requests that this Court enter an order for Plaintiff and against Defendants, granting Plaintiff the following relief:

(a) That equitable relief be issued in the form of a permanent injunction prohibiting any ongoing exclusionary conduct, and unreasonable anticompetitive agreements entered into, by Defendants;

(b) Awarding Plaintiff damages for losses suffered as a result of Defendants' actions in an amount to be proven at trial, including, but not limited to, compensatory damages for Plaintiff's lost sales and profits on its generic version of Thiola, and the disgorgement of any benefit unlawfully retained;

(c) Awarding Plaintiff treble damages pursuant to 15 U.S.C. § 15, along with all other available statutory damages;

(d) Awarding Plaintiff its costs and expenses, including attorneys' fees and costs; and,

(e) Granting Plaintiff such other and further relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiff Spring Pharmaceuticals, LLC demands a trial by jury as to all issues of right to a jury.

Dated: February 10, 2020

/s/ Robert F. Ruyak
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